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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,398	02/18/2004	Bruce K. Redding JR.	04-40081-US (879388.20001)	4352
7066 7590 04/18/2007 REED SMITH LLP 2500 ONE LIBERTY PLACE 1650 MARKET STREET PHILADELPHIA, PA 19103			EXAMINER GRAY, PHILLIP A	
			ART UNIT	PAPER NUMBER
			3767	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/18/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/782,398

Applicant(s)

REDDING, BRUCE K.

Examiner

Phillip Gray

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This office action is in response to applicant's communication of 1/29/2007.  
Currently amended claims 1-14 and newly added claim 15 are pending and rejected.

#### ***Response to Arguments***

Applicant's arguments filed 1/29/2007 have been fully considered but they are not persuasive. Applicant argued that amended claims overcome the Babaev reference, due to the addition of the language "such that said signal emitting device is at least in indirect contact with said tissue". Examiner is maintaining the position that Babaev reference does indeed disclose that the signal-emitting device is at least in indirect contact with said tissue (indirect contact). Examiner draws applicant's attention to paragraph [0005] and paragraph [0006] of the Babaev reference. At the very least the "air" would be at intermediate medium that could be the "something" which attaches the signal emitting device in contact with the tissue. Applicant is reminded that during examination, claim limitations are to be given their broadest reasonable reading. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); In re Prater, 415 F.2d 1393, 1404-1405, 162 USPQ 541, 550-51 (CCPA 1969). Examiner is taking a broad definition of "indirect contact". Examiner is viewing the word "indirect" as meaning "not in a direct course or path; deviating from a straight line; roundabout" or "coming or resulting otherwise than directly or immediately, as effects or consequences". Under these definitions examiner is of the position that both Babaev

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and Tachibana are in at the least indirect contact between the signal emitting device and the tissue.

Further more, the Tachibana reference is given to show additional teachings of direct and indirect contact between signal emitting device and tissue, see rejections below.

Applicant also argued that the rejections under 102 and 103 for the depending claims 2-14 are in error in response to the amendments to claim 1. Claim 1 does not overcome the prior art (per discussion above, rejections below) and nor do depending claims 2-14. Therefore all rejections are proper and the amended pending claims 1-14 stand rejected.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Babaev (U.S. Patent Application Number 2002/0156400). Babaev shows an ultrasonic method for treating wounds, specifically chemical or fire burns (paragraph 50), by applying a drug (antiseptic or antibiotic), oil, saline, distilled water or the like (paragraph 17) to the

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wounded tissue (including skin, paragraph 5). The Babaev method shows of affixing at least one ultrasonic signal emitting device (ultrasound transducer 20), substantially adjacent to at least one substance (drug, saline, ect. in reservoir 24) and applying an ultrasonic signal to the substance so as to effect movement of substance into tissue (paragraph 17 and 18) and the signal emitting device is at least in indirect contact with the tissue (see paragraph [0005]-[0006]). Babaev further discloses that the ultrasonic signal has a frequency range between about 1 to 10000 kHz (paragraph 44) and an intensity range between 0.25 w/sq.cm to 3 w/sq.cm (paragraph 5). Babaev discloses that the waveforms may be modulated, pulsed, rectangular, trapezoidal, or triangular (claims 11-17); which would include two alternating waveforms, square waveforms, or saw tooth waveforms or a combination.

Claims 1 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Tachibana et al (U.S. Patent Number 5,315,998). Tachibana discloses an apparatus and method for treating tissue (as carried out by the apparatus in figure 3) comprising situating a transdermal apparatus (15) in at least partial contact with tissue (directly or indirectly as in the Tachibana apparatus), situating medicament (17) substantially adjacent to or partial within the transdermal apparatus, affixing at least one ultrasonic signal emitting device (16) in at least partial contact with the transdermal apparatus, and applying at least one ultrasonic signal emitted from the signal emitting device, so as to effect movement of at least a portion of the medicament into the tissue (as described in paragraphs beginning at column 4 line 47 for example). Tachibana discloses that in

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addition to the active medicament saline may be used as well, (see paragraph at column 2 line 32).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babaev in view of Bommannan (U.S. Patent Number 5,115,805). *Babaev* discloses the claimed invention except for the containment of a substance within an absorbent transdermal apparatus, and release of at least a portion of a substance when a signal is applied to an absorbent transdermal apparatus. Bommannan teaches that it is a known method to have a patch type transdermal drug delivery device whereby the substance contained in the patch is delivered to the target tissue by ultrasound signal, as set forth in column 7 line 62 to provide an effective and convenient mode for transdermal drug delivery. It should be noted that Bommannan discloses an apparatus and method where the ultrasonic emitting transducer is located within the absorbent transdermal drug delivery device, which would be a patch or similar attachment system (column 7, line 38). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method for treating burns as taught by Babaev with a containment and application transdermal drug delivery patch as taught by

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Bommannan since such a modification would provide the method of treating burns with a transdermal drug delivery containment patch and application method for providing an efficient mode of drug delivery.

Claims 12 and 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Babaev in view of Mauchamp (U.S. Patent Number 6,537,224). Babaev discloses the claimed invention except for a stacked transducer array coupled to the absorbent transdermal apparatus. Mauchamp teaches that it is known to use a multiple layer stacked transducer array, as set forth in paragraphs 20 through 25, to provide a more compact size and superior electro-acoustic performance. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus to treat burns as taught by Babaev with stacked transducer array as taught by Mauchamp, since such a modification would provide the method and apparatus for treating burns with a stacked array of transducers coupled to the absorbent transdermal apparatus for providing a more compact size and superior electro-acoustic performance.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Babaev in view of Zhang (Patent Application Number 2002/0096973). Babaev discloses the claimed invention except for the cymbal type flat transducer. Zhang teaches that it is known to use cymbal type flat transducer as set forth in paragraphs 13 and 65, to provide a directional ultrasonic radiation pattern for drug delivery. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus for treating burns and drug delivery as taught by

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Babaev with a cymbal type flat transducer as taught by Zhang, since such a modification would provide the method and apparatus for treating burns and drug delivery with a flat cymbal transducer capable of generating a directional radiation pattern.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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PAG

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

